Esophageal Stricture Compliance Measuring Device

Biomedical Engineering Design 200/300

William Stanford- Team Leader/BSAC
Dan Frost – BWIG
Tom Fleming – Communicator

Client: Mark Reichelderfer, MD
Department of Gastroenterology, UW Medical School

Advisor: John Webster, Ph.D.
Professor Emeritus, Department of Biomedical Engineering

December 12, 2007

Table of Contents

Abstract

Esophageal strictures occur in the lower esophagus just above the cardiac sphincter. The main cause of strictures is acid reflux disease but they can also be caused by cancer and genetics. Larger strictures cause the opening of the esophagus to shrink, making it difficult to swallow, and require dilation. The goal of this project was to create a device and software that can, in real-time, measure and display the compliance of esophageal strictures by measuring the pressure applied by the stricture to the dilation balloon simultaneously with the volume of liquid inside the balloon. LabView was used to create this program that displays a real time graph of pressure applied vs. volume graph. This real-time graphing capability, coupled with data collected in future testing, will allow doctors to know when to stop a dilation procedure before perforating the esophagus, thereby preventing the dangerous consequences of such a complication.

Background

The esophagus (Figure 2) is the tubular structure connecting the throat to the stomach. A specialized muscle called the lower esophageal sphincter (LES, Figure 1) and located at

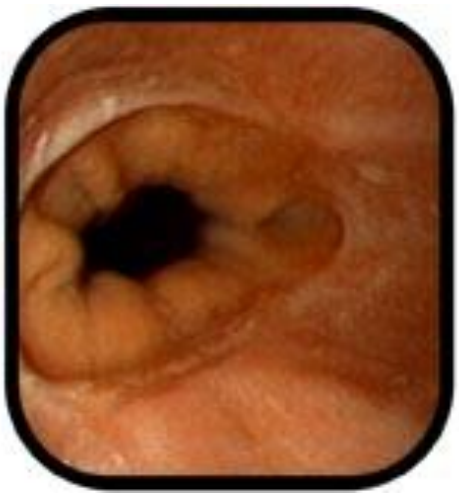

Figure 1: Lower Esophageal Sphincter (from:http://www.gicare.com/pated/eiegnmle.htm)

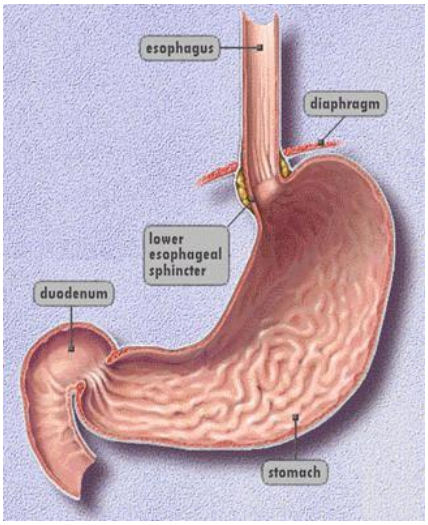

Figure 2: Stomach and Esophagus (from: http://intmed.muhealth.org/gast/patient_resource/anatomy_function/esophagus.html)

the distal end of the esophagus regulates the passage of food and liquid into the stomach. When working properly, the LES relaxes to allow foods and liquids to pass into the stomach and then contracts to prevent stomach acids and the digested food to move back up the esophagus.

Occasionally, the LES fails to contract properly and allows digestive enzymes and stomach acids to reflux into the esophagus. This acid reflux damages the tissue of the lower esophagus. When damage occurs frequently, repeated healing cycles cause scar tissue to build up in the esophagus. This scarring causes a narrowing of the esophagus called an esophageal stricture (Figure 3). About 70-80% of esophageal strictures are caused by this type of gastroephageal reflux (Vasudeva, 2006). Other causes of these strictures include the ingestion of corrosive substances like cleaning solution, damage caused by endoscopy, and infection by bacteria or viruses, but each of these accounts for only a small fraction of stricture occurrences.

A person with an esophageal stricture will experience some difficulty swallowing, called dysphagia. In mild cases, this dysphagia is limited to the swallowing of solid foods, but in more severe cases even swallowing liquids can be extremely painful.

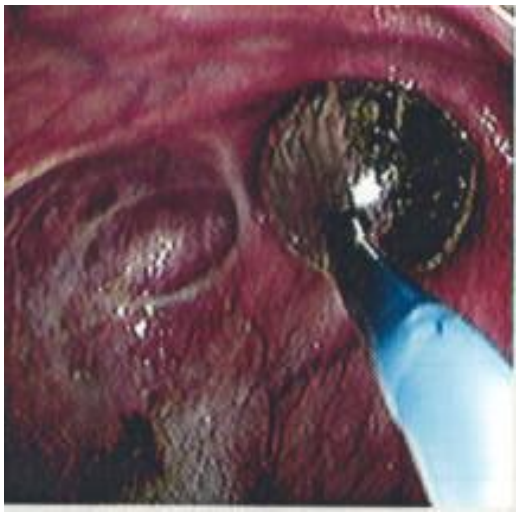

Figure 3: Balloon Dilation of an Esophageal Stricture

The most common treatment method for these strictures is called balloon dilation (Figure 3). This

procedure utilizes a balloon attached to a syringe via a narrow plastic tube. The balloon is pushed through the esophagus and into the narrow stricture opening. Saline solution is then delivered to the balloon from the syringe to gradually widen the area of the stricture. Typically, the diameter stricture is widened anywhere from 5-20 mm (Vasudeva, 2006). Though this procedure widens the stricture, there is a large rate of stricture recurrence, and any single patient may have to undergo this procedure many times in his or her lifetime.

Most of the time this procedure is safe, but in some cases, the dilation can cause a perforation of the tissue of the esophagus. These cases of perforation can be very dangerous as they can lead to infections and even death. A study of the compliance (the change in volume per unit of applied pressure) of the esophageal stricture could provide valuable insight into the kinds of applied pressures that generally cause perforation. If compliance could be measured effectively, these dangerous cases could be minimized or even eliminated.

Problem Statement

Little work has been done with the compliance of esophageal strictures. If more was known about the compliance of different size strictures, doctors could categorize them and develop trends that would lead to more efficient treatment options. Currently, there are no devices on the market that measure the compliance of esophageal strictures. The objective of the client and the team is to create a device that can measure the compliance of esophageal strictures. The output of the device should provide a real time graph of

compliance that can be viewed during the procedure and also be capable of altering the procedure team to any perforation of the esophagus that requires immediate action.

Design Requirements and Constraints

The device and the software used to display information while using it require some capabilities which are critical when monitoring what is happening during an esophageal dilation surgery. Quite simply, it must measure volume of saline that is being injected into the dilation balloon and also the pressure the balloon exerts on the esophagus. With this, it must then graph in real time these results, creating a tissue compliance curve that can be used by the physician to maintain a safe dilation process.

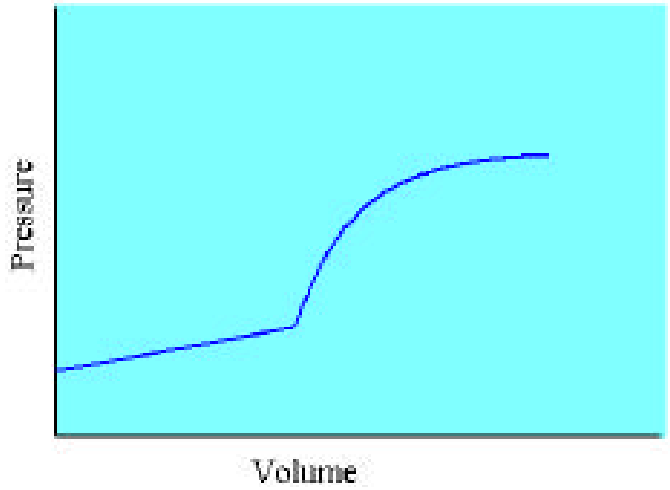

Figure 4. This graph shows an example curve with volume and pressure measurements. The sharp increase in the slope of the curve occurs when the balloon comes into contact with the walls of the esophagus.

This curve is an example of what our software may display to the physicians in real time. Eventually, the compliance data should be accurate to two significant figures past the decimal.

Other design requirements have to do with maintaining the simplicity of the procedure for the physician, and not adding on to the process of dilation that they are already performing. This means that the device is an addition to the procedure, and will not change what the doctor does at all, just give more information about what is happening during the procedure. One thing that the design must be capable of doing is to inform the physician of a perforation in the esophagus, and provide a warning to stop immediately. This adds safety to the procedure. In addition, the software must be able to be run on the computers already being used in hospital GI units. This eliminates the need for hospitals to spend money on new equipment when it is possible to use what they already possess. Finally, the design needs to be able to be easily used in a hospital setting. This means that it must be compact as to not get in the way during surgery, and also it must be aesthetically pleasing for when it becomes commercially available.

Though safety is usually a major issue when dealing with devices that collect data on humans, it is not a large factor in the design requirements. This is simply because the data collection does not add any more risk to the patient. The dilation surgery is already being performed, and the addition of a data collection device is just providing means to analyze the surgery as it is happening. Any risk from contamination or from damage to the esophagus from the balloon inserted is a result of the surgery itself, and not from the device.

Design Option 1: LabView

LabView is a software program developed by National Instruments for graphing, measuring and analyzing. It uses an image based programming language where the user chooses the desire function for a menu and drags it onto a back panel. The back panel is used for designing the program while the front panel displays the actual program, including graphs and controls. The program also contains linear operators that can convert the signal inputs into different units and then display these converted units in a graph. LabView also has the ability to filter the incoming signal and display the graph on the filtered information.

LabView has many advantages that would help with the project. The first is its ability to graph in real time. The client has specified that the data must be displayed in real time so he can view the data during the procedure and have a warning of sharp decreases in slope to alert him of a perforation of the esophagus. Along with this, LabView can graph two inputs on the same graph: one on each axis. Even if the program did real time graphing, it would be of no use if it could only graph one input at a time. Secondly, the program can convert easily from volts into units of pressure and volume. This is important because nurses and doctors will not have to do any converting in the procedure room or after the surgery is complete. The graph can be printed as is and studied without needing to do many, time consuming conversions.

LabView's disadvantages lie in the actual writing of the program. While it is image based and no computer code language is needed, the amount of images and programming

options is large. The knowledge assumed of the programmer is higher than that of a second or third year undergrad with no programming experience. Thus, the amount of time needed to spend learning the program is great and may be too much for the scope of this project. A meeting with Amit Nimunkar was held to discuss LabView and how to go about writing out program. After the meeting, it seemed that it would be possible to write the program. National Instruments is also teaching a class on LabView in the coming week which will be helpful in learning to use LabView properly. This will help immensely in writing the program. The only other disadvantage of LabView is its cost of $1199 for base, $2399 for full and $4099 for professional. If it is necessary to buy separate licenses for each computer being used, it could become quite expensive. LabView professional may have an application distribution option that would allow one program to be purchased and then installed on many computers. This would be ideal for use in a hospital setting.

Design Option 2: BioBench

BioBench is software application program designed specifically for physiological data acquisition and analysis by National Instruments. It is used for graphing and analysis of data, particularly from the fields of the life sciences. The software is designed so that no programming language or know-how is required, and it is compatible on nearly any PC, whether it is a desktop or a laptop. A feature called "Playback Mode" enables the user to be able to watch any previously acquired data trends as necessary, which allows for deeper analysis of the data. Overall, the software is useful for acquiring, storing, displaying and analyzing data in the life sciences fields.

BioBench has some advantages that were considered in the decision making process. Something that is important to any potential users of the device would be the simplicity and amount of background knowledge required in order to work the software along with the device itself. BioBench is a turnkey application, which means that no programming is required at all. This is important because anyone could simply acquire the software and begin collecting data immediately. Because a major goal of the project is to not interfere with the surgery being done by using complicated software, this is very advantageous. Also, another advantage to the software comes in the form of multiple inputs, and BioBench is capable of using sixteen input channels. For the device, two inputs would be necessary, one for pressure and the other for volume of saline displaced from the syringe. Though the device only requires two, the fact that BioBench supports sixteen is another advantage of the software. Perhaps the biggest advantage of this software is its affordability. The program runs at $995.00 for a Windows-based application. However, this can be used on any PC, which is economically beneficial.

BioBench also has some disadvantages which were considered when choosing the final design. Unlike LabView, BioBench does not possess a unit conversion function. This is important because it cannot translate volts into units for pressure and volume. Doctors or nurses should not have to do this themselves, or have another other program to do it for them because that adds to the complexity of the surgical process, and again keeping the surgery as easy as possible for the physicians is very important. Also, BioBench may have a playback mode, but it lacks a graphing function. All data must be exported into Microsoft Excel and then may be graphed using that program. This means that real time

graphing is not a possibility with BioBench. Because this is the client's main design requirement, the lack of the real time graphing feature is a major disadvantage for this software. Having to convert units with another program adds more complications to the dilation surgery, and not being able to detect sharp changes in graphs that may mean esophageal perforation immediately adds risk.

Design Option 3: Pasco

Pasco's DataStudio software is a tool for data collection and analysis. The software is designed to have "plug-and-play" data collection capabilities. Using Pasco's PasPort sensors and computer interface devices, one can connect a sensor directly to a computer and record data in real time. The software itself allows such manipulations as customizing scaling and displays, statistical data analysis, and importing and exporting data. This software and sensor technology is often used in introductory biology and physics laboratories to demonstrate principles of physical and biological principles.

Despite its ease of use and real time collection capabilities, there are a number of drawbacks that make Pasco's software insufficient for our purposes. First, the software is only capable of collecting from sensors manufactured by Pasco. Though the list of sensors they manufacture includes a pressure sensor, their pressure sensor is not usable for measuring liquid pressure. Also, though easy to use, the software lacks advanced programming capabilities that would allow us to program perforation warnings into the data collection process. Finally, the use of Pasco would require that all hospitals using our device purchase Pasco's interfacing system in addition to their software, adding an extra and ultimately excessive cost to our design.

Design Matrix

The design matrix (Figure 5) was created to aid in the decision making about what software program to use to write the program to graph volume vs. pressure. The categories were chosen based on the design constraints mentioned. Each category was given a weighting out of 100 total points according to its importance. Real time graphing was given the highest weighting of the four categories because the completed prototype needs to be able to graph the information in real time. Inputs and unit conversion were ranked next in importance. If the program was not capable of working with the sensors of the prototype, then it could not be used, even if it could graph in real time. Ease of use refers to the writing of the needed program. This, and cost, where least important because they have less to do with the actual functioning of the software program. After adding together the scores of each software program, the design matrix indicated that LabView is the best program because it has the best real time graphing and is compatible with the inputs.

	Weight (out of 100)	**LabView**	**BioBench**	**Pasco**
Graphing Capability	70	70	10	60
Ease of Use	5	2	3	4
Inputs	10	9	9	0
Unit Conversion	10	8	1	6
Cost	5	1	2	5
Total	100	90	25	75

Figure 5: Design matrix of the three design options

New Design: LabView Circuit

As stated previously, LabView was chosen as the software program to use for the real time graphing. After further research, it was determined that the pressure sensor already had an amplification device built into it so no additional amplification circuit was necessary. Both the pressure transducer and the linear potentiometer required a 5V power supply, which was provided by the electronic power supply device. The outputs of each sensor were attached to separate channels of a National Instruments Educational Laboratory Virtual Instrumentation Suite (ELVIS) device. The ELVIS fed the output signals into the computer so they could be captured with LabView.

The LabView software program was configured to capture the signals using a Data Acquisition element. When placed in the LabView block diagram, the element processes the input signals. The number of input channels can be selected and the sample rate can be set to capture at a rate fast enough to read all the data points. From here, the signal is split into two, one from the pressure transducer and one from the linear potentiometer. In order to convert the voltage signal to the correct units of volume and pressure, the signals were run through a mathematical operator. The operators were assigned a constant that corresponded to the number of volts per milliliter or atmosphere. To determine the volume relationship, the linear potentiometer was attached to a volt meter. The voltage at different volume amounts was recorded and graphed in Excel. The graph showed a linear relationship and there were 11.189 milliliters per volt. To determine a pressure voltage relationship, the ideal gas law $pV = nRT$ had to be used. Knowing that the density of air is $1.2\ \frac{kg}{m^3}$ and that there are $1 * 10^{-6}\ m^3 per\ milliter$ the mass of the air in the balloon

could be found. Dividing the mass by the molar mass of air, 0.0029 kg, the number of moles, n, could be found. Plugging this into the equation and solving for volume gave a pressure reading of 0.999 atm. By recording the voltage value at this point, it was determined that there are 22.72 atmospheres per volt.

The two modified inputs were then run to a xy graph, with the volume going to the x axis and pressure going to the y axis. A while loop is then placed around the entire program to keep the program running for an infinite amount of time. This approach, however, only graphs a single point, not a continuous curve. In order to graph the curve of all the data points, the data must be continuously run through the program. This is achieved through the use of arrays and shift registers. An array combines two data inputs into one output. Shift registers allow a signal to be inserted into the while loop, and looped back to the beginning so that data can be continuously collected. By inserting the signal from the Data Acquisition element and the shift register into the array, new and old data points are combined into one signal. The array and shift register system is applied to both outputs of the Data Acquisition element. This new output signal is run to the xy graph. A continuous curve could now be displayed because all of the data is being inserted into the graph the entire time it is running.

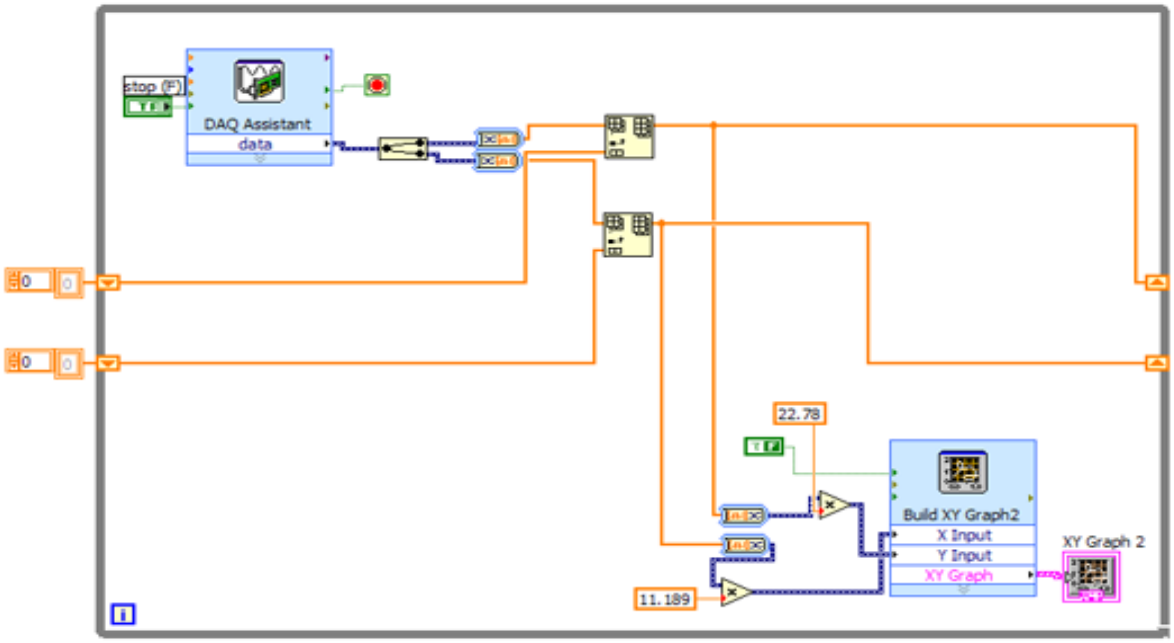

Figure 6: The complete LabView circuit used to display the real time pressure vs. volume graph.

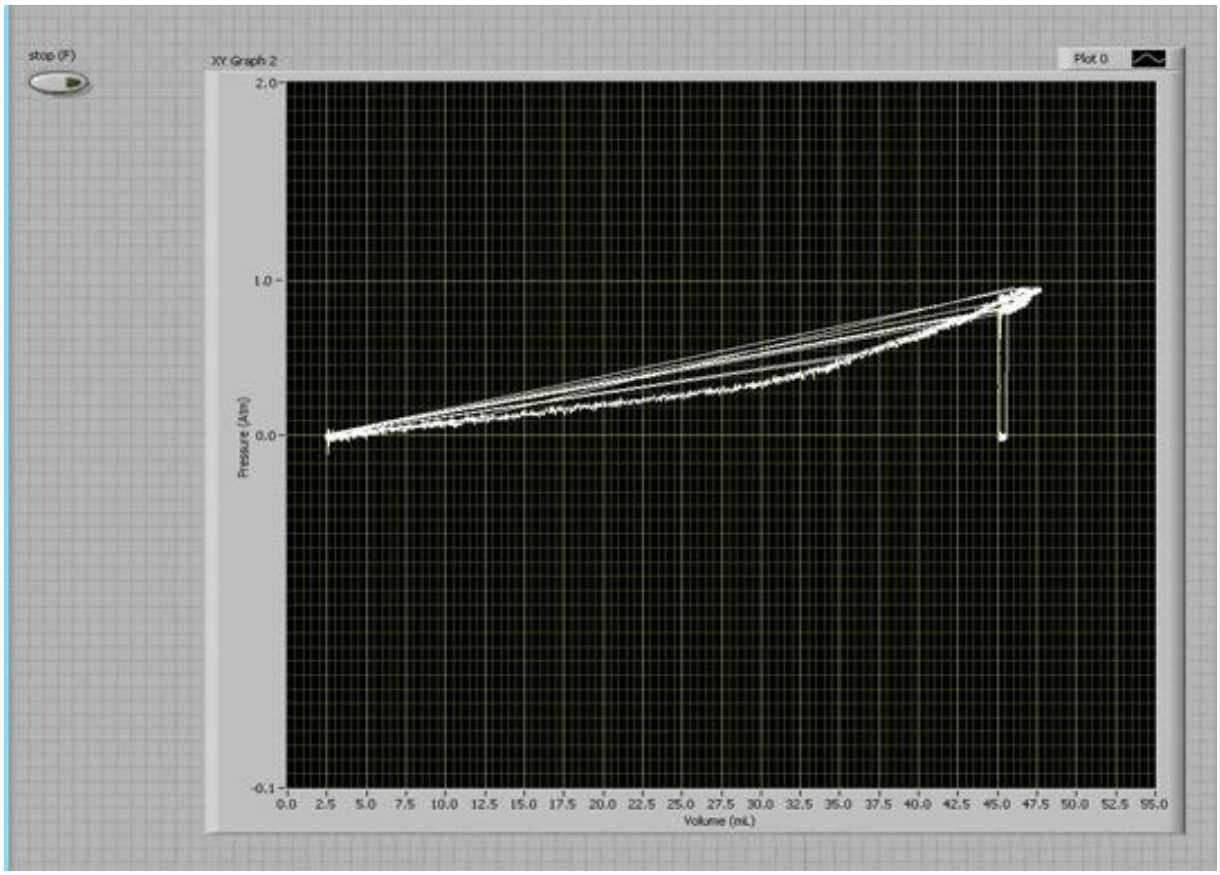

Figure 7: The pressure vs. volume graph recorded with the described LabView circuit. The x-axis is in milliliters of volume and the y –axis is in atmospheres of pressure. The peak pressure is just below 1 Atm.

The base program allows for modification in the future. Once testing begins, it may be applicable to view other types of graphs as well. Using mathematical operators, it would be easy to convert the signals into stress and strain. In the future, more testing will have to be done to determine the correct sampling rate.

Ethical Concerns

Overall, there are very few ethical concerns regarding the use of our device in a hospital setting, both in the testing phase and in full implementation. Balloon dilation procedures are already performed in hospitals across the country on a daily basis, using the same method that will be used with our compliance-measuring device. When performing these procedures currently, doctors use syringe guns similar or identical to the one which serves as the basis for our device to inflate the dilation balloon with saline solution. Our device is designed to be used with the disposable balloons used in each procedure. The only changes that have been made that might affect doctors performing the procedure are the potentiometer attached to the side of the syringe gun, and the pressure sensor connected at a T-joint at the end of the syringe. These additions will add extra weight to the dilation apparatus. However, since the procedure is non-invasive, the procedure does not involve any fine motor movement on the part of the doctor, or call for extreme precision which the extra weight might interfere with. Therefore, even in its current prototypical form, the device should be completely safe to use in testing and collecting data on dilations that must be performed, adding no risk beyond that inherent in the procedure as it is currently performed.

Concerns arise, however, in testing on animals. In order to collect reliable data about the compliance curves resulting from perforation of an esophagus, the dilation of the esophagus of animals used in testing will necessarily be perforated. These perforations could cause severe negative effects on the animals tested, and could even kill some of them. This is the exact complication the device is intended to prevent in humans. Therefore, ethical concerns will arise at forcing this very complication on animals. The Humane Society, for example, is pushing for legislation to be enacted by 2020 which will eliminate all pain and suffering of animals use in biomedical testing ("Pain and Distress," 2007).

If animal testing is chosen as the most viable method of testing the device and acquiring the necessary compliance data to properly calibrate the hardware and software, these ethical concerns will have to be addressed. To minimize the ethical dilemmas arising from animal testing, great care will be taken to prepare for the negative consequences of the testing procedure so as to give the animals being tested the best chance for survival and recovery. Also, alternatives to animal testing will be explored, such as acquisition of esophagi from human cadavers. If these esophagi can be obtained and maintained in a state similar to the esophagi in vivo, they could be more effective sources of accurate tissue material data than animal esophagi. Acquiring these cadaver esophagi in a form which mimics living tissue may be much more difficult than testing on live animals, and therefore, may not be as viable as the animal testing, despite animal testing's ethical problems.

In terms of the actual implementation and distribution stage of our device, the only ethical concerns which will arise should be in places where our device is not used.

If our device prevents or reduces the frequency of esophageal perforation and the infections that arise from it, it would be unethical for doctors and hospitals that perform dilation procedures to not purchase one for use. From a developer's perspective, we do not wish to make the device so expensive that the price of the safer procedure which uses the device is inaccessible to the common patient. Though the device will incur costs greater than those of current dilation methods, the extra costs will not be so large as to greatly increase the costs to patients who require the procedure.

Future Work

The future work of this project consists of a few main phases. The first of which is to obtain all of the necessary components of the device, starting with a new sensor which was ordered a week prior to the final poster presentation. Unfortunately, it was not ordered at an earlier time due to the fact that it took a substantial amount of time to realize that it was broken, and that the setup was not incorrect. Once the sensor is obtained, it will need to be connected to the existing device and tested to be sure that it works with the LabView circuit. This does not present any foreseeable problems because the circuit was originally setup using the same sensor, only now it will be fully functioning. Once the sensor is working properly, additional testing of the device can begin.

Testing will be a key part of the progression of this project. In order to know if it will work on humans in the hospital, testing will first be performed on animals or other with other viable methods. Once the initial testing has been completed satisfactorily, approval for human testing will need to be granted, which will allow actual tests on patients who are undergoing the dilation procedure. This will involve IRB approval and

a patient consent form. An advantage for this project is that there is no additional risk to the patient beyond the risk from the dilation procedure itself, since the procedure is not being altered. This will ease the process of gaining approval for testing.

A possibility to consider in the future is altering the device so that it operates and responds to the level of stress the esophagus will be under. The goal is to successfully dilate the esophagus while keeping the level of stress beneath the yield strength of the tissue. The yield strength is defined in engineering as the stress at which the material begins to deform plastically (Yield). Any deformation in the plastic region is deformation that may be irreversible. If the yield strength is reached during dilation, the patient may be at risk for infection and in some cases this may be lethal if too much damage is done. An idea for the future is to learn the yield strength of esophageal tissue and to have the device fill the balloon slower as the stress builds, until finally it shuts down altogether before reaching the yield strength.

The final phase will involve finalizing the design. First of all, all of the elements of the device will need to be housed in a way that eliminates any external wires for either the pressure sensor or the linear potentiometer. Also, a power supply will need to be added internally so that the extra bulk of an external power supply will not be potentially in the way of the surgeons while they perform the operation. Another thing to be done is to configure an alarm that will sound when the stress is becoming too great or when the esophagus is at the point where it could potentially perforate. This will alert the physician that the procedure needs to be stopped immediately so no damage is done to the tissue.

Finally, an interface will need to be created to display the graph of the tissue compliance that is easy to read for physicians and compatible with computers that hospitals will have in their operating rooms. Ideally, this will involve the creation of software that is capable of displaying data from two inputs and combining them into one graph. Although LabView does this, there may be a problem with the high cost of this software.

Conclusion

The project has made great strides towards the testing phase. Past software programs did not allow real time graphing, making the prototype useable but not capable of achieving its overall all purpose: allowing doctors to monitor tissue compliance during dilation procedures and have an alert to warn them of possible esophagus perforation. With this semester's addition of a LabView program that can display a real time graph, the device is nearly ready for testing. The addition of the new sensor and a few refinements of the software program will make the device ready for testing. In the future, test results will allow a correlation between the maximum stress an esophagus can withstand before perforating. This will allow the configuration of an alarm to alert doctors that the procedure needs to be stopped. If testing yields significant results, the device could one day be in used in procedure rooms around the world.

References:

Hale, A. et al. (2002). Barostat to Measure Esophageal Strictures.

Insturments, N. (2007). *BioBench*. Retrieved October 22, 2007, from BioBench: Products and Services: http://sine.ni.com/nips/cds/view/p/lang/en/nid/1454

Insturments, N. (2007). *BioBench: Physiological Data Acquistion and Analysis*. Retrieved October 22, 2007, from BioBench: Products and Services: http://www.ni.com/pdf/products/us/1msw155a.pdf

Insturments, N. (2007). *LabView: 20 Years of Innovation*. Retrieved October 22, 2007, from LabView: http://www.ni.com/labview/

Kirking, H. et al. (2002). Barostat to Measure Esophageal Strictures.

"Pain and Distress." Animals in Research. The Humane Society of the United States.

2007. 11 December 2007 <http://www.hsus.org/animals_in_research/pain_distress/Pain-

amp-Distress.html>.

Seashore, K. et al. (2006). Device for Dilating Esophageal Strictures.

Vasudeva, R., Deal, D. R. (2006). *Esophageal Stricture.* Retrieved October 22, 2007, from WebMD: Emedicine: http://www.emedicine.com/med/topic744.htm.

Yield (engineering). 2007. http://en.wikipedia.org/wiki/Yield_(engineering).

October 27, 2007

William Stanford
Dan Frost
Tom Fleming

Device for Dilating Esophageal Strictures

Function: The current prototype is designed to measure the tissue compliance of an esophageal stricture during balloon dilation. A syringe gun is used to inject distilled water in a balloon. As the syringe is depressed, a sensor attached to the side of the gun and to the top of the syringe measures the change in volume. The potentiometer measures the change in volts as the arm of the sensor gets shorter. The pressure sensor is attached at a t joint at the end of the syringe. Water is then able to go into the pressure sensor and the balloon. The two sensors are attached to a computer, which can store the data. Currently the data is stored in mV and needs to be inputted in a separate program after collection, such as Xcel to get output readings of mL or m^3 for the volume and Atmosphere or Pascal for the pressure. The readings can be stored on any computer that is capable of readings inputs from the sensors and running the BioBench or other programs.

Client Requirements: The client has three goals for the project. The first is to make the design aesthetically pleasing. This will get the device ready to be used in a hospital setting. This includes putting the sensors in a plastic casing and binding the wires into a single wire. The second is to write a software program that can measure the pressure and the volume in real time and make a graph on the computer screen. An alarm program will accompany this software to alter the doctor and nurses to perforation of the esophagus. The last goal is to gain approval for human testing. This requires writing an IRB protocol and gaining approval from the IRB board.

Design Requirements:

1. **Physical and Operational Characteristics**
    - **a.** *Performance requirements:* The data recording will be added on to a device that is already in common use in hospitals. The addition of the sensors must not interfere with the procedure and should be capable of being implemented in any GI procedure room in the country. The volume of the syringe will be under 70 mL as this is as far as the syringe can be pulled back. Pressure readings from past groups have given a range of 1-8 Atm.
    - **b.** *Safety:* The sensor device is essentially a no risk addition to the procedure. The operation is already being done and the device only measures the surgery and does not change it.
    - **c.** *Accuracy and Reliability:* The pressure and volume sensors need to be able to make a smooth graph that is readable to the operating team. The device should be significant to 2 significant figures after the decimal.

d. *Life in Service:* The sensors will be good for the lifetime guaranteed by the manufacture. The syringes are replaced as needed readily from hospital supply. A new balloon dilator is used with every patient.

e. *Ergonomics:* The only restriction on the device is the length of the wires connecting it to the computer and the force needed to pull the trigger of the syringe gun.

f. *Size:* The device has to be able to be held in one hand or mounted and capable of being moved around the operating room.

g. *Aesthetics, Appearance, and Finish:* The final product should be similar in color and texture to the syringe gun the sensor is mounted on.

2. Production Characteristics:

a. *Quantity:* The current goal is to produce one prototype. The future goal is to have the device available and in every GI procedure room in the country.

b. *Target Product Cost:* The materials for the sensors cost around $100. The syringe gun is the most expensive of the prototype at around $500. The syringe and balloon dilator are bought in mass quantities and are disposable.

3. Miscellaneous

a. *Standards and Specifications:* With one of the goals to begin human testing, approval from the UW-Madison Institutional Review Board will be necessary to incorporate the device into the procedure.

b. *Patient-related Concerns:* All team members will need to be HIPAA certified to work with the data collected. Each patient will be assigned a number and the list of the names and numbers will be kept inside a locked box where only the doctor can access it. People working with the data will only be able to see the number of the patient.